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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : A. Bayati

Serial No. : 10/053,279 Examiner: Michael Hartley

Filed : January 17, 2002 Group Art Unit: 1616

For : THERAPY FOR FUNCTIONAL DYSPEPSIA

I hereby certify that this paper is being facsimile transmitted to The U.S. Patent and Trademark Office, Alexandria, VA 22313-1450, on October 15, 2004.

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35,372 — PTO Reg. No.

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Attn: Examiner M. Hartley

Art Unit: 1616

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with 37 CFR §1.56 and in accordance with 37 CFR §§1.97 and 1.98, it is requested that the two (2) references listed on the attached Form PTO/SB/08A be made of record in this application. Copies of the references are enclosed.

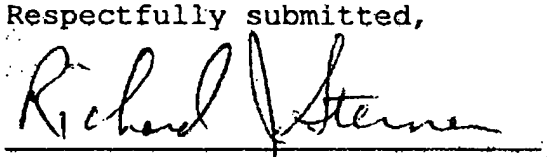
In accordance with 35 CFR §§1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made or that the information is material to patentability as defined in 37 CFR §1.56(b).

The two references cited herein are the Master of Science Thesis of Maria Nordling and an abstract thereof. The abstract was printed and copies were distributed to appropriate faculty members at the University of Uppsala. The thesis itself was presented orally to approximately ten people. The thesis was not distributed, nor was it housed or cataloged in the University library.

These documents are submitted under 37 CFR §1.97(c), i.e., after the mailing of a first Office Action but prior to the mailing of a final Office Action. The Commissioner is hereby authorized to charge the fee set forth in 37 CFR §1.17(p) to Deposit Account No. 23-1703. Any other fees which may be due for any reason in connection with this communication may likewise be charged.

Dated: October 15, 2004

Respectfully submitted,



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Enclosures

PTO/SB/08A (08-03)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/053,279
Filing Date	January 17, 2002
First Named Inventor	A. Bayati
Art Unit	1616
Examiner Name	Michael Hartley
Attorney Docket Number	1103326-0678

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages/Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	1	M. NORDLING, "A Comparative Study of Gastric Distension in Different Rat Strains," Master of Science Thesis, University of Uppsala, Sweden, 2000	
	2	M. NORDLING, Abstract of Cite No. 1	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORM TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Abstract

Functional dyspepsia (FD) is characterized by nausea, vomiting, bloating, feelings of fullness early satiety and epigastric pain, but the pathology is unknown. In many of the FD-patients, the proximal stomach is unable to relax in response to food. In others, the gastric motility or gastric emptying is impaired. Almost all of the FD patients report that they have been exposed to one or more social stressors for more than a year. It has been shown that stress alters the motility, and it may have altered the gastric motility in FD patients, leading to dyspeptic symptoms.

In order to investigate if stress also affects gastric accommodation in animals, the gastric volume response to balloon distension was compared in Sprague Dawley (SPRD) male and female rats and Wistar Kyoto (WKY) male rats, the latter being a rat very sensitive to stress.

A barostat system was coupled to a balloon, which was inserted into the stomach of the rat via a fistula. The barostat system was then connected to a program which produced the desired pressure: 10 min ramp distension up to 10 mmHg followed by 10 min tonic distension at 10 mmHg and then a decrease to 1 mmHg (the same as the starting pressure). The pressure and volume from the experiments were entered in a data program, and different parameters were then calculated from these data.

There were no significant differences between the groups in the basal tone or elasticity in the stomach muscle. Neither were there any signficant differences between the groups regarding the threshold values when the adaptive reflex-mediated relaxation had started. It was also shown that there were no significant differences in any of the parameters between the SPRD female and male rats. However the adaptive relaxation was significantly impaired in WKY rats compared with both the SPRD male and female rats.

It was shown that the properties of the stomach muscle basal tone and tension were not impaired in WKY rats. The adaptive relaxation in response to distension was, on the other hand impaired, which indicates a defect in the reflex pathway in WKY rats.

The results show that the WKY rat, which is considered to be very sensitive to stress, has impaired gastric relaxation in response to gastric distension.This is in agreement with the pattern seen in some dyspeptic patients who have impaired adaptive relaxation related to a meal.